Director's Forum

Developing a Business Plan for Critical Care Pharmacy Services

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Critical care medicine has grown from a small group of physicians participating in patient care rounds in surgical and medical intensive care units (ICUs) to a highly technical, interdisciplinary team. Pharmacy's growth in the area of critical care is as exponential. Today's ICU requires a comprehensive pharmaceutical service that includes both operational and clinical services to meet patient medication needs. This article provides the elements for a business plan to justify critical care pharmacy services by describing the pertinent background and benefit of ICU pharmacy services, detailing a current assessment of ICU pharmacy services, listing the essential ICU pharmacy services, describing service metrics, and delineating an appropriate timeline for implementing an ICU pharmacy service. The structure and approach of this business plan can be applied to a variety of pharmacy services. By following the format and information listed in this article, the pharmacy director can move closer to developing patient-centered pharmacy services for ICU patients.

Critical care medicine has grown from a small group of physicians participating in patient care rounds in surgical and medical intensive care units (ICUs) to a highly technical, interdisciplinary team. Pharmacy's growth in the area of critical care is as exponential. Today's ICU requires a comprehensive pharmaceutical service that includes both operational and clinical services to meet patient medication needs. A 2006 survey of the status of critical care pharmacy services in the United States showed that a majority of hospitals provided basic services to the ICU (eg, drug distribution, order verification by pharmacists); higher level services such as patient care rounds and direct involvement of pharmacists in critical care drug therapy management were less than optimal.¹

As directors of pharmacy focus their efforts on meeting the recommendations of the American Society of Health-System Pharmacists' (ASHP's) Pharmacy Practice Model Initiative (PPMI), expanding services to the critical care areas will be critical to

address high-risk and high-cost medication management. Most hospital administrators will require the pharmacy director to present a business plan or proposal to them for review that provides sufficient background and evidence to expand pharmacy services in the ICU. This step is often overlooked or is not given adequate attention, causing delays and misunderstandings and leading to elimination or reduction of services. By placing programs and plans in the form of a business proposal, pharmacy directors increase the likelihood their services will be funded by stakeholders.

This article describes the elements of a business plan for expanding pharmacy services and provides pertinent information for each element as it applies to developing ICU pharmacy services. This business plan and approach can be modified for other pharmacy services. By following the format and information listed in this article, the pharmacy director can move closer to implementing patient-centered pharmacy services for ICU patients.

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ELEMENTS OF A PHARMACY BUSINESS PLAN

A key step in the approval of any new pharmacy service is the business plan. The business plan can be viewed as both an operations plan and a planning document. A 2007 review of writing a business plan for a new pharmacy service published by the American Pharmacists Association is an excellent resource.² The business plan describes a program, details the costs and steps in implementation, and lists the measures for success. The business plan can also provide a singular and powerful message to employees and senior management as to the vision, mission, and values of the pharmacy service.

The business plan is divided into several sections; these recommended sections along with brief explanations are shown in **Table 1**. There is no single way to develop a business plan, but keeping the proposal clear and simple will improve its ability to be understood, especially by administrators with minimal clinical background. Before writing the business plan, the pharmacy director must have a clear vision of the “end product.” For example, in this case the pharmacy director must have a clear vision for the scope and delivery of the ICU pharmacy service. This vision can be developed by reviewing the literature and interviewing service stakeholders. Stakeholders include physician

intensivists, administrators, pharmacy staff, nursing staff, and, where appropriate, patients. This is a sample vision for the ICU pharmacy service: *This business plan is significant because provision of pharmacy services by appropriately trained and credentialed critical care pharmacists providing comprehensive medication management has been demonstrated to improve patient outcomes in a cost-effective manner.*

A business plan for ICU services also usually assumes that the pharmacy department provides basic services to an ICU, including medication distribution, inventory control, some simple clinical services (medication reconciliation, pharmacokinetic dosing programs), and order management and verification by pharmacists. Second, the proposal assumes a high level of acceptance of the pharmacy's recommendations and trust between the services of medicine, nursing, and pharmacy. In most cases, the proposal for ICU pharmacy services builds on an established relationship that is focused on improved patient care and outcomes while providing effective cost controls.

SAMPLE BUSINESS PLAN FOR ICU PHARMACY SERVICES

As part of the template for establishing critical care pharmacy services, it will be important for the

Table 1. Elements of a pharmacy business plan

Element	Brief description
Executive Summary	A clear statement of your proposal, along with the benefits of the service, proposed activities, costs, and timeframes
Background	This section provides the literature review necessary to justify your service, or any historical context leading to this point. This section should be concise but thorough and include any pertinent benchmarking data, institutional data supporting a clinical service, and results of surveys or other agencies requiring a change in clinical services.
Proposal	This is the “meat and potatoes” of the proposal and focuses on the current state and the vision and details to achieve a future state. Operational details, costs, and work flows are a critical part of this section. Finally, after funding is secured, it is essential to include a timeline as to when the service will be started.
Benefits	Calculates a return on investment, whether financial or otherwise. The focus on determining the outcomes of the service (impact on cost and quality) should be the focus of this section.
Summary	Reinforces the other sections and summarizes the entire proposal. Displaying a summary using graphics (table, figures) helps to provide a clear picture of what is being proposed. Make sure any assumptions in the proposal are reviewed in this section.
Appendices	Optional, but can contain valued documents such as financial statements, letters of support, research papers, and pertinent policies and procedures.

pharmacy director to make sure the executive summary is presented clearly and simply. It is also critical to develop buy-in with stakeholders by being very thorough in the literature review; the director should identify any accreditation standards or certifications that would be helpful to justify the service. Funding of the service may also be a joint effort. So pharmacy directors should consider asking physicians or nursing colleagues to support part of the full-time equivalents (FTEs); these FTEs will help to make the work of the medical and nursing staffs more efficient. Finally, savings may not always be calculated in terms of supplies (drugs, laboratory tests). Reassigning or expanding the duties of another provider (eg, physician, nurse practitioner) may have some unintended savings that can be documented by adding pharmacy services to the ICU.

Sample Executive Summary

This proposal requests 2 specialty-trained ICU pharmacists (2.0 FTE) to establish pharmacy services within the surgical ICU. The pharmacists will work 12-hour shifts as 7 days on, 7 days off rotation. Proposed hours of coverage are from 0700 to 1900, representing the ICU's busiest times. The benefits include improved patient care and patient safety by ensuring improved patient throughput, protocol management, education, and transitions of care along with improved provider satisfaction and reduced ICU medication costs. Pharmacy services in the institution's ICU are currently limited to participation in code situations, stocking of department medications, and answering questions from ICU clinicians who have phoned the central pharmacy. Patient-specific questions related to medications are currently handled by nonspecialized pharmacists who are *not* part of the interprofessional ICU team and are *not* involved in the direct care of the patients. The critical care pharmacist will be responsible for comprehensive medication management that will include activities such as participating in patient care rounds, training and education of all health care providers, direct medication management activities (dosage adjustments), and quality improvement and research programs. The cost of the program is [insert amount] based on the salary and benefits of 2.0 FTE pharmacists; the estimated return on investment (ROI) is [insert amount]. The service can be running with full resources within [insert number] months, with various steps in approval of positions and budgeting to be completed by first quarter of FY2017.

The Department [insert department name or others as agreed upon] is supporting this initiative with funding for a postgraduate year 2 (PGY2) critical care residency (\$[insert amount]/year) and the Department of Nursing [or others] has provided a strong letter of support identifying improvements in patient flow that are likely to occur with a pharmacist specialist working on the interprofessional team. The College of Pharmacy [if no College, then another supporting partner may be included] has agreed to partially fund a third critical care specialist position in FY2018 that will allow enhanced student participation in this service and ensure 100% coverage of patients in the ICU by pharmacy.

Proposed ICU Pharmacy Service

Needs assessment. Medication errors comprise a major subset of medical errors that result in many deaths each year in addition to other consequences related to morbidity, length of stay, and costs. The adverse drug events (ADEs) resulting from these medication errors are avoidable and unacceptable consequences of defects in the health care delivery system. Medication errors and associated ADEs are particularly problematic in ICU settings, due to its fast pace and an environment that leads to miscommunication and little time for clearly evaluating clinical situations.³ Further, most of the medications considered to be high alert or high risk in acute care settings are commonly administered in the ICU environment.

Landmark studies by the ADE Prevention Group that were conducted in ICUs *without* critical care pharmacists found that there were 6.5 ADEs and 5.5 potential ADEs (ie, near misses that did not result in patient harm) for every 100 admissions.⁴ These rates were approximately twice as high as those found in non-ICU settings.⁵ The system problem that was identified as the most common cause of these ADEs was lack of appropriate dissemination of knowledge of medications.⁶ Of note, the ADEs in these studies were identified by clinician self-reporting and chart reviews by nurse investigators. Even higher rates have been reported using continuous direct observation techniques at the bedside. For example, there were 36.2 preventable ADEs for every 1000 patient-days identified in the Critical Care Patient Safety Study, or 1 preventable error for every 5 doses of medication administered in another investigation using a direct observation approach.^{7,8} In both of these studies, most errors occurred at the prescribing stage of the medication use process. It has been estimated that the

cost to the health care system for each ADE ranges from \$6,000 to \$9,000.⁹ For our surgical ICU [or applicable unit – complete as your institution has data], this estimate would be 24 patient beds x 365 days = 8,760 patient-days x 36.2 preventable ADEs per 1,000 patient days = 317 preventable ADEs at \$6,000 to \$9,000 each for a range of \$1,902,317 to \$2,853,000.

Error reduction at the local hospital level is based largely on specific quality improvement measures implemented after ADEs have been identified through a traditional voluntary reporting system. However, voluntary reporting systems are retroactive and have disadvantages with respect to under-reporting of events either not appreciated by the clinician or thought to be of minimal consequence to the patient or near misses. Payers, accreditation agencies, governmental agencies, and a variety patient safety advocacy groups desire and often mandate more proactive multidisciplinary approaches to error prevention.

Proposed level of service. A position paper by the Society of Critical Care Medicine (SCCM) and the American College of Clinical Pharmacy (ACCP) published in 2000, which was subsequently revised and enhanced into an opinion paper published in 2011 by a larger group of critical care pharmacists that included members of ASHP, listed 3 categories of critical care pharmacy services: fundamental, desirable, and optimal.^{10,11} *Optimal* pharmacy services are comprehensive and require a specialized approach to care that is integrated with all other disciplines.¹¹ The recommended credentials for pharmacists providing critical care services include PGY2 training or equivalent experience, board certification in critical care, and advanced cardiac life support (ACLS) certification in addition to the usual credentials associated with licensure to practice. This is consistent with research that demonstrates that critical care pharmacy specialists perform significantly more interventions to prevent patient harm and optimize medication use than nonspecialists.¹² Therefore, an unmet need exists in our health care system.

We intend to fulfill this unmet need for optimized medication management by developing and implementing critical care pharmacy services. This proposal will move us from a fundamental provider to an optimal provider of pharmacy services in the surgical ICU. *This project is significant because provision of pharmacy services by appropriately trained and credentialed critical care pharmacists providing comprehensive medication*

management has been demonstrated to improve patient outcomes in a cost-effective manner.

Sample ICU Pharmacy Service Description

The critical care pharmacist will be responsible for comprehensive medication management that will include:

1. Participation in interprofessional rounding, patient care meetings, and code arrests.
2. Performance of patient admission medication histories, medication reconciliation, and patient profile reviews. This proposal will allow us to move from 45% to 100% coverage of this key metric in surgical ICU patients.
3. Involvement in transfer/discharge medication consultation. The critical care pharmacist will focus on moving to oral meds from IV and on reducing medications that result in longer term ICU stays, such as sedatives and pain medications, to minimize ICU length of stay.
4. Involvement in medication use review (as appropriate).
5. Service as a mentor/educator to trainees (pharmacy, nursing, and medicine).
6. Support of quality improvement and research initiatives.
7. Service as an educator and medication information resource that is easily accessible to ICU clinicians.
9. Performance of medication order review for cost effectiveness and appropriateness.
10. Implementation and demonstration of cost-savings initiatives related to medications.
11. Service as a leader for critical care pharmacy services.

Sample Value of the Proposed Service

One of the key aspects of optimal critical care pharmacy services is the ability of the pharmacist to participate on interprofessional rounds in the ICU. A landmark study published in *JAMA* in 1999 found that including a pharmacist on patient care rounds with subsequent availability throughout the day led to a 66% reduction in preventable ADEs by prescribing physicians.¹³ Importantly, almost 99% of the pharmacist's recommendations were accepted by the physicians. Subsequent studies have confirmed that medication errors and associated ADEs are more likely to be identified, and therefore prevented, by the type of direct observation

that would occur by having critical care pharmacy specialists involved in direct patient care activities. In one study involving patients in an adult ICU, an increased number of potential and actual ADEs were identified by direct observation by a pharmacist versus the numbers reported in other studies that utilized traditional voluntary reporting, chart reviews, or solicited incident reporting.⁸ All of the potential ADEs and approximately two-thirds of the actual ADEs in this study were judged to be preventable. The errors occurred at various stages of the medication use process. There was one preventable error for every 5 doses of medication administered.

A wealth of studies are now available attesting to the patient safety and economic benefits of interprofessional critical care pharmacy practice.¹⁴ Shared decision making that includes patients (or their surrogates) and members of an interprofessional team has been endorsed by major critical care organizations, and pharmacists have been recognized as integral members of the team by other clinicians and administrators.¹⁵⁻¹⁷ Additionally, critical care pharmacists performing higher level services have improved job satisfaction.¹⁸

The data collected by critical care pharmacists will be amenable to economic analyses. In one investigation, the type of activities performed by an ICU-based pharmacist was evaluated.¹⁹ There were a total of 129 interventions documented over a 4.5-month period. The majority of interventions were identified during chart review (40%) and rounding (39%) activities. The 2 investigators evaluating the interventions determined that the potential cost avoidance of the documented interventions was between \$205,919 and \$280,421. Interventions identified during rounding and chart review were most likely to achieve the greatest impact on cost avoidance. In a more recent randomized interventional comparative trial, critical care pharmacists provided recommendations that were accepted 83.1% of the time and were cost-beneficial in 53.8% of patients (benefit-cost ratio of 25:1, 95% CI, -5:1 to 94:1).²⁰ These results are consistent with perceptions of nonpharmacist prescribers who perceive financial as well as clinically impactful services provided by ICU pharmacists.²¹

Sample Quality and Safety Metrics

Policies and procedures will be developed for the evaluation of the critical care pharmacy specialists.

The evaluation process will include an assessment of the quality and safety metrics listed below. For interventions by the pharmacist, the electronic health record will be used to document the type of intervention, the seriousness of the issue identified that required intervention, the estimated cost impact of the intervention, and the estimated time to perform the intervention. In addition to evaluating cost savings and cost avoidance by the pharmacists' interventions, a formal cost-benefit analysis of the service will be performed at 1 year following the deployment of the critical care pharmacists.

Quality and safety metrics of the proposed service will be based on the types of metrics utilized and recommended in the peer-reviewed literature discussed in this plan:

- Number and types of interventions
- Patient safety improvements
- Process and quality of care improvements (eg, order sets, guidelines, protocols, medication use evaluations)
- Clinical outcome evaluations (eg, length of stay, readmissions)
- Committee involvement
- Educational activities
- Economic evaluations
- Stakeholder satisfaction that includes peer review
- Number and quality of mentoring experiences for trainees
- Honors or awards received by specialists or service
- Dissemination (eg, presentation, publication) of quality improvement and research findings

Sample Timelines

A proposed timeline for the hiring, orientation and training, deployment, and evaluation of the critical care pharmacists is as follows. (It may be helpful to include this timeline on a Gantt chart for a clearer picture of implementation timeframes.)

- Hire the pharmacists with the required credentials while continuing to garner support from key stakeholders (eg, physicians, nurses, administrators)
- Month 1: Orient pharmacists to health care system and key health care personnel and provide them with the resources (eg, security identification, computer passwords) necessary for their clinical practice.

- Month 2: Pharmacists are deployed to ICU to initiate an interprofessional direct patient care practice that includes documentation of agreed upon metrics.
- Months 3 and 4: Formative discussions and assessment of services involving ICU pharmacists and pharmacy administrator will be held.
- Month 6: Summative evaluation of ICU pharmacists and assessment of service will be conducted by pharmacy administrator, including identification of lessons learned with possible changes in ongoing implementation.
- Month 12: Summative evaluation of ICU pharmacists and assessment of service performed by pharmacy administrator, including identification of lessons learned with possible changes in ongoing implementation. Findings are relayed to hospital administration.

EVALUATION OF THE PROPOSED SERVICE

Sample Description of Costs

Of most critical concern to administrators and physician executives is the cost of the ICU pharmacy services. Describing one-time costs and recurrent costs separately can assist in designating what resources to request at what times. In addition, a plan that builds the service over time by adding resources in an incremental fashion are usually more successful than the "Big Ask" approach. Some considerations for costs include the following:

- \$180,000 personnel expense (\$150,000 salary; \$30,000 fringe costs)
- \$1,500 one-time computer expense
- \$2,000 annual travel and educational expenses
- Desk space
- Telephone

It is difficult to accurately predict any return on investment as the ICU pharmacy service begins operations. Most often the pharmacy director will predict a certain reduction in drug expense to offset the expenses of the new service; that is not recommended as some use of expensive medications may justifiably increase. A pharmacist involved in the team may suggest the best practices around treating sedation, infections, and other conditions. These conditions may require more costly medication that may increase the pharmacy budget but decrease the hospital's overall costs.

A good rule of thumb is to develop a small group of stakeholders to review some key metrics of the ICU service at regular intervals and develop some "wins" in the area of improved medication distribution efficiencies, reduced medication errors, improved nurse and provider satisfaction, and patient safety improvements resulting from the pharmacists' activity.

CONCLUSION

As directors of pharmacy focus their efforts on meeting the recommendations of the ASHP's PPMI, expanding services to the critical care areas will be critical to address high-risk and high-cost medication management. Today's ICU requires a comprehensive pharmaceutical service that includes both operational and clinical services to meet patient medication needs. The business plan to justify pharmacy positions on the patient care team in the ICU that was described in this article can be applied to a variety of pharmacy services. By adapting the format and information to their institutions, pharmacy directors can move closer to developing patient-centered pharmacy services for ICU patients.

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